

IN THE UNITED STATES AND TRADEMARK OFFICE

IN RE Application of

Josée Hamel, et al.

Serial No : 09/884,465

Filed : June 20, 2001

Title: NOVEL STREPTOCOCCUS ANTIGENS

DECLARATION OF DR. DENIS MARTIN

I, Denis Martin, declare that:

1. I am a co-inventor of the invention of the subject Patent Application No. 09/884,465, entitled "*Novel Streptococcus Antigens*."
2. I am a citizen of Canada, residing at 927 Place Séguin, Ste-Thérèse, Qc, Canada, J7E 4P5.
3. I am Director, Research, at ID Biomedical Corporation of Quebec.
4. I have read the Office Action mailed December 1, 2004, in the above-referenced application. I had undertaken the following experiments which address the issues raised by the Examiner therein.
5. The six chimeric peptides listed in the table below were generated using the procedures disclosed in the specification of the above-referenced application. In particular, NEW 17 and NEW 28 were generated as disclosed in Example 1 of the specification, and the procedures and information disclosed in Example 10 and table 22 of the specification were used in the generation of VP109, VP94, VP112 and VP113. The production and purification procedures used in the production of these recombinant chimeric peptides for these experiments were the same as those described in Examples 1 and 22.

Groups of female BALB/C mice (Charles River) were immunized as described in Example 1. Ten to fourteen days following the last immunization, the mice were challenged intranasally with 10^4 to 10^5 CFU of *S. pneumoniae*. The data are shown in the table below.

The data clearly indicate that the chimeric peptides, NEW 17, NEW 28, VP94, VP109, VP112 and VP113 efficiently elicit a protective immune response against experimental pneumonia, which is comparable to the protection observed after immunization with fragments derived from the parental recombinant proteins as presented in Tables 14 and 21 of the specification.

Experiment	Immunogen	Alive : Dead	Days to death post-infection
1	none	0 : 8	2, 2, 2, 2, 2, 3, 2, 2
	NEW 17	6 : 2	>14, >14, >14, >14, >14, 7, 6, >14,
2	none	1 : 7	4, 4, 4, >14, 4, 5, 4, 4
	New 28	8 : 0	8 X >14
3	none	0 : 8	4, 3, 4, 4, 4, 4, 5, 3
	VP 94	8 : 0	8 X >14
4	none	0 : 6	5, 5, 5, 4, 5, 4
	VP 109	6 : 0	6 X >14
5	none	0 : 8	4, 4, 1, 4, 5, 5, 5, 5
	VP 112	5 : 3	>14, 6, 5, >14, 6, >14, >14, >14
	VP 113	6 : 2	>14, >14, >14, 5, >14, >14, >14, 10

6. The ordinarily skilled practitioner would find sufficient guidance in the specification to enable the generation of a genus of immunoprotective peptides having at least 85% sequence similarity to SEQ ID NO. 332 commensurate in scope with the claims of application Serial No. 09/884,465. The specification teaches that SEQ ID NO. 332 is composed of two immunoprotective peptide fragments separated by an amino acid linker, and provides the sequence of several examples of immunogenic peptide fragments

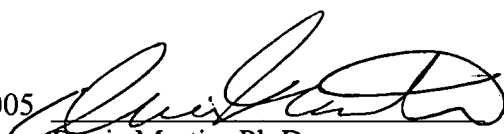
that can be incorporated into a chimeric peptide of the invention and provides sufficient guidance for the generation of other chimeras. The specification also teaches how to test the chimeras *in vivo* using routine immunological procedures.

The generation of chimeric peptides having 85% sequence identity to SEQ ID NO. 332 does not require undue experimentation on the part of an ordinarily skilled practitioner, nor is it undue experimentation to test the chimeras for immunoprotective properties.

The relative skill in the art is quite high. The skilled practitioner would recognize from the sequence data provided in the specification, from the disclosure of the location of surface exposed fragments of BVH-11 and BVH-3, and from the disclosure of several immunoprotective fragments within the cell surface exposed regions of BVH-11 and BVH-3 (including the sequences thereof) that a large number of immunoprotective chimeras can be generated by varying the SEQ ID NO. 332 by up to about 15%.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 27, 2005



Denis Martin, Ph.D.